

YT-1601 Dog Medallion

Date: November 13, 2008

EPA File Symbol.: 39039-RU

DP Barcode: D353229

Pest: Fleas and Ticks; Repels Mosquitoes and Biting Flies

Chemical: Piperonyl butoxide (20%)  
Zeta-cypermethrin (10%)

Shaughnessy  
Number: Piperonyl butoxide 067501  
Zeta-cypermethrin 129064

Purpose: Request is to review efficacy data for a dog medallion product to control fleas and ticks.

**MRID:**

47398901

**Citation Reference:** Cunningham, J. (1996) The Efficacy of Insecticide Medallion Formulations for the Control of Fleas Infesting Dogs: Final Report. Project Number: AR/95/B, YTD/195. Unpublished study prepared by Agresearch Consultants, Inc. 49 p.

47398902

**Citation Reference:** Hair, J. (1998) The Efficacy of Insecticide Medallion Formulations for the Control of Ticks (*Rhipicephalus sanguineus*): Final Report. Project Number: OK/98/A. Unpublished study prepared by Nu-Era Research Farms. 48 p.

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**Citation Reference:** Hair, J. (2004) The Efficacy of Insecticide Dog Medallion Formulations for the Control of Fleas and Ticks Infesting Dogs. Project Number: OK/04/B. Unpublished study prepared by Nu-Era Research Farms. 160 p.

GLP: No

Branch Supervisor: Meredith Laws, Branch Chief

Team Reviewer: Linda DeLuise

Efficacy Reviewer: Joanne S. Edwards, M.S. Entomologist

Joanne S. Edwards  
11/13/08

## **BACKGROUND:**

Request is to review efficacy data for a dog "medallion" product. This is the first use of zeta-cypermethrin on dogs. The directions for use state to attach the medallion to D- ring on collar using the provided connector. The medallion is to swing freely from the D-ring. (Note: there is no pictorial description of the medallion or the connector.)

There are two sizes of the medallion: 3.5 gram for dogs weighing 14-29 pounds and 7.5 gram for dogs weighing 30- 70 pounds

The directions state to use two 7.5 gram medallions for dogs over 70 pounds. The directions also state the product may not be applied to dogs weighing less than 14 pounds.

Label claims include:

- Kills ticks for up to 2 months
- Kills fleas for up to 5 months
- Provides Continuous long term protection against pests
- Repels Mosquitoes and Biting Flies
- Full protection against hard-to-kill ticks will build up within a few days and will last for up to 2 months.
- For maximum population control of fleas and ticks, it is necessary to treat not only the pet but also its environment
- Waterproof

## **REVIEW OF DATA**

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Study Design:

- Four groups of three dogs each: (1) non-swinging medallion fixed to collar- 7 gram; (2) free-swinging medallions- 7 gram (identical in formulation and similar in design to the model in thickness and means of medallion to what is proposed for registration; (3) free-swinging medallions of different thicknesses than what is proposed for registration); and (4) untreated control.
- Dogs housed indoors in individual, heated, chain-link, fenced, concrete floored runs.

- Cat flea Infestation: on days -1, -2, 6, 13, 20, 27, 35, 41, 48, 76, 106, 134 and 152. (100 adult cat fleas per dog)
- Visual counts of live fleas 24 hrs after infestation (see pg 9 of report; dead fleas not counted)
- Comb counts of live fleas three days after infestation (see pg 9 of report; dead fleas not counted)
- For Group 2 (7 gram free-swinging medallion), live flea counts were also taken on days 107, 135 and 153
- Percent control determined by:  $[(\text{live fleas on untreated} - \text{live fleas on treated}) / \text{live fleas on untreated}] \times 100$

### Reported Results:

The weights of the three dogs in the 7 gram treated group were 25, 30 and 32 pounds.

Table 1. # Live Fleas (rounded values) and % Control from 3 Dogs With 7 Gram Medallion

Day	Total # Fleas		% Control
	Control	Treated	
1	171	34	80
3	139	5	96
7	204	34	83
9	248	18	93
14	197	3	99
16	219	5	98
21	289	1	100
28	236	1	100
36	173	0	100
44	252	0	100
51	236	0	100
79	202	0	100
107	206	5	98
135	176	5	97
153	191	6	97

(Results not included for other treatment groups since not applicable to the product being proposed for registration.). Raw data not included in report (e.g., dead flea counts).

The results showed the 7 gram medallion controlled fleas for the duration of the study (153 days). This study is considered a range-finding study. These data will not support claims for flea control, since (1) only three dogs, and (2) the proposed product is intended to be marketed in a 3.5 gram medallion for dogs weighing up to 14- 29 pounds. The average weight of the 3 dogs in this study was 29 pounds.

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**Study Design:**

- 4 dogs in each treatment group (Group 1- 2.5 gram medallion; Group 2- 4 gram medallion; Group 3- control)
- At various time intervals, dogs were infested with 50 Brown dog ticks (*R. sanguineus*) (see pg 11-12 of report)
- 24 hours after infestation, visual counts were taken (report does not state whether live and/or dead ticks)

**Reported Results:**

The average weight of the four dogs in the 4 gram group was 25.6 pounds. The weight range was 24.5 pounds to 26.9 pounds.

Table 2. Average # Brown Dog Ticks (rounded values) and % Control With 4 Gram Medallion

Day	Average # Ticks (Control)	Average # Ticks (4 gram)	% Control (Based on Tick)
Sept 15	19	14	26
16	15	4	72
18	14	2.5	82
22	15	0.3	98
24	17	0	100
29	15	1	97
Oct 1	15	0.3	98
6	23	0.5	96
8	23	0.5	97
22	23	0.3	99
Nov 12	18	5.5	69
Dec 3	24	11.5	53

Only results for the 4 gram medallion reported, since product to be marketed is 3.5 gram for dogs in 14-29 pound weight class. The report does not indicate whether the counts were of live or dead ticks, or both.

For the four dogs treated with the 4 gram medallion (in weight class 14-29 pounds), the performance standard of  $\geq 90\%$  was not met until a week after attaching the medallions. Brown tick control of  $\geq 90\%$  was achieved for about one month.

Although a 4 gram medallion was used in this study, the directions for use state to use a 3.5 gram medallion for dogs 14-29 pounds

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**Reference:** Control of Fleas and Ticks Infesting Dogs. Project Number: OK/04/B.  
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**Study Design:**

- 8 dogs in each treatment group (4 male and 4 female in each)  
Group 1- 2.5 gram medallion  
Group 2- 4 gram medallion  
Group 3- 4 gram (with mylar, collected eggs for test on hatching; not applicable to product proposed for registration)  
Group 4- control
- Dogs housed individually in indoor/outdoor pens
- At various time intervals, dogs were infested with 100 cat fleas and 50 Brown dog ticks (see pg 11-12 of report)
- After 24 hours of infestation, counts were taken were made. The report does not indicate how the counts were taken (e.g., combing or visual observation of parted hair)

**Reported results:**

For the 4 gram medallion treatment group, the average weight of the animals was 23.4 pounds with a range of 25 to 37.2 pounds (25, 34.8, 27.5, 30.3, 32 29.7, 28.4 and 37.2 pounds). For the 2.5 gram medallion treatment group the average weight was 23.4 pounds with a range of 19 to 24.8 pounds.

Table 3. Cat Fleas (rounded values) (average of "dead" fleas in parentheses)

Date	Average # Cat Fleas Control	Average # Cat Fleas 2.5 gram	% Control	Average # Cat fleas 4 gram	% Control
April 2	64	40 (1)	38	27 (1)	59
3	60	25	59	18	71
7	76	26	66	17 (1)	78
8	67	15	78	10	85
14	74	7 (1)	91	3	96
15	61	4	93	2	97
21	75	7 (1)	91	3	96
22	69	4	94	11 (1)	98
May 5	79	7 (1)	91	2 (1)	98
6	66	4	94	1	99
19	72	7 (3)	90	2 (1)	98
20	63	4	95	0	100
June 2	77	16 (2)	79	8 (2)	89
3	71	7 (1)	90	4 (1)	95
16	76	14 (1)	82	5 (1)	94
17	68	7	89	2	97



30	76	19 (1)	75	8 (2)	90
July 1	71	11	85	5	93
July 14	77	19	76	16 (1)	79
15	72	11 (1)	85	12 (1)	83

(Note: the 2.5 gram medallion is not being proposed for registration).

Greater than 90% flea control was not achieved until after about two weeks for the 4 gram medallion treatment group. After that,  $\geq 90\%$  control lasted for about 2 1/2 months (with exception of one data point)

Although a 4 gram medallion was used in this study, the directions for use state to use a 3.5 gram medallion for dogs 14-29 pounds (average weight was 23.4 pounds in this group).

Table 4. Brown Dog Ticks (rounded values) (average of "dead" ticks in parentheses)

Date	Average # Ticks Control	Average # Ticks 2.5 gram	% Control	Average # Ticks 4 gram	% Control
April 2	12	5 (1)	56	4	66
6	19	6 (1)	69	2	87
7	19	4	78	1	93
13	21	4	82	0	98
14	21	4	80	0	99
20	18	3 (1)	81	3	81
21	18	3	85	3	83
May 4	19	5 (1)	76	3 (1)	84
5	19	4 (1)	79	3	86
18	21	3 (1)	86	2 (2)	89
19	21	3 (1)	87	2 (1)	92
June 1	18	11 (2)	41	4	76
2	13 (1)	8 (2)	40	3 (1)	78
15	21	8 (1)	61	4 (1)	81
16	20	8 (1)	63	3 (1)	84
29	19	9 (1)	55	8 (3)	60
30	19	7 (1)	65	7 (2)	65
July 13	21	9 (1)	59	7 (1)	65
14	20	7 (1)	64	6 (10)	72

Note: the 2.5 gram medallion is not being proposed for registration

For the 4 gram medallion treatment group,  $\geq 90\%$  control of Brown dog ticks was achieved only at the one and two week observation periods (with exception of one data point on May 19).

## CONCLUSIONS

There is no objection to registration of a **4 gram medallion** for use on dogs **weighing between 14 and 29 pounds** for **control of fleas for up to three months** and **control of Brown dog ticks for up to one month**. The product must be reformulated to 4 grams, to be identical to the medallions used in these studies.

No direct reference to "kill" is allowable, since flea/tick kill was not demonstrated (most studies did not include counts of dead fleas or ticks).

The product was shown to be slow-acting, so the label must state this.

Insufficient data were submitted to support the 7.5 gram medallion for large dogs (only 3 dogs tested using a 7 gram medallion). In order to support a claim for control of fleas and ticks using the 7.5 gram medallion for dogs weighing 30- 70 pounds, at least two field studies must be submitted, with each study containing a minimum of six dogs tested at the highest range in the weight class, e.g., six 65-70 pound dogs.

No data were provided for dogs weighing over 70 pounds. In order to support a claim for control of fleas and ticks using two 7.5 gram medallions, at least two field studies must be submitted, with each study containing a minimum of six dogs tested at the highest range in the weight class (as identified on the label).

**Required label Modifications:**

- Add "This (4 gram) product may only be used on dogs weighing between 14 and 29 pounds. May not be used on dogs weighing less than 14 pounds, or greater than 29 pounds."
- Add "This product is slow-acting", or "Takes a few days to show effects."
- Revise the statement "Kills fleas for up to 5 months" to read "Controls fleas for up to three months."
- Revise the statement "Kills ticks for up to two months" to read "Controls Brown dog ticks for up to one month."
- Revise the statement "For maximum population control of fleas and ticks, it is necessary to treat not only the pet but also its environment" to read "For control of fleas and ticks, it is necessary to treat not only the pet but also its environment"
- Delete the statement "Provides continuous long term protection against pests" (heightened efficacy claims).
- Delete the statement "Repels Mosquitoes and Biting Flies" (no data submitted).
- Delete the statement "Full protection against hard-to-kill ticks will build up within a few days and will last for up to 2 months" (insufficient data).
- Delete the term "Waterproof" (no data).